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(54) **Intravascular hydrogel implant**

Intravaskuläres Hydrogel-Implantat

Implant à hydrogel intravasculaire

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Description

This invention relates to an implant device comprising a hydrophilic, nontoxic, hydrogel material capable to be permantently inserted into a vascular structure such as a vein, artery or vessel to treat a localized abnormal wall of the structure, and an apparatus for delivery and placement of said implants.

From WO-A-80/01460, a catheter is known to widen a constricted body duct which is made of plastic material and covered by hydrophilic plastic substances capable to suck up liquids and thereby to increase its volume. This prevents the catheter from being transported in the body duct. After use, the catheter is withdrawn.

The medical field of interventional neuroradiology, includes procedures for the treatment of a localized abnormal wall of a vascular structure, such as arteriovenous fistulae and intracranial aneurysms in a vein, artery or vessel. These procedures are delicate, complex and essential to mitigate potential life-threatening fistulae and aneurysms. More specifically, an arteriovenous fistual is basicallly an opening between the walls of a closely adjacent vein and artery, resulting in a diversion of blood flow from the higher pressure artery to the lower pressure vein. The flow of blood thus diverted, does not reach portions of the body downstream of the fistula.

An aneurysm is basically a ballooning of a blood vessel at an abnormal wall portion of the vessel which is stretched or distended into a shape referred to as a "sac". An intracranial aneurysm is such a ballooning of a vessel in the brain which could result in loss of brain function or death. Current implants for treating these localized abnormal wall portions of the vascular structure include packing the abnormal wall of the vascular structure with detachable latex or silicone balloons or electrically detachable platinum coils. In the case of intracerebral aneurysms, the placement of any material (balloon, coil) into the thin-walled aneurysm sac has been known to cause catastrophic rupture of the aneurysm, either by direct perforation, or due to changes in the pressure/flow dynamics during manipulation of the aneurysm. In treating large aneurysms, multiple balloons/coils are needed, with resultant intra-aneurysmal blood clot formation. This clot may either: 1) lyse, causing reappearance of the aneurysm with new risk of hemorrhage; or 2) fragment, with clot emboli causing varying degrees of cerebral ischemia, including devastating cerebral infarction.

In the case of carotid-cavernous fistulae, difficulties may arise if the vascular structure is too small to accept a balloon or coil delivery catheter. If the opening is large, the balloon/coil may "herniate" into the artery, resulting in stenosis/occlusion of the internal carotid artery or of one or more of its branches.

Because of these potential disastrous complications and the technical difficulties of these implants, they may be performed only by highly trained individuals.

Metallic stents are not favored for use in vessels and ducts because they rust and are not effective.

SUMMARY OF THE INVENTION

Among the objects of the invention are to provide an implant device and an apparatus for the delivery, placement and implantation of the implant device.

The invention is defined in the claims. With invention, a hydrogel material is used for the treatment of certain vascular abnormalities, such as aneurysms, fistulae, or tears of a vessel wall. The apparatus uses a fluoroscopically guided catheter via the percutaneous puncture of an access vessel. A kit may contain essential aparatus required to practice the invention, to thereby significantly improve treatment of vascular abnormalities.

In accordance with the invention, a vein, artery or vessel with a peripheral wall defining a cavity and having a localized abnormal wall is treated by inserting a device of a hydrogel material into the cavity; and
then hydrating and expanding the hydrogel material until the device occludes the abnormal wall area.

The hydrogel device may be used to treat vascular structures, namely, veins, arteries, and vessels, with abnormal walls such as: fistulae, aneurysms, dural malformation, vascular malformation, and fibromuscular dysplasia. More particularly, vascular structures include: brachiocephalic artery, carotid artery, vertebrae artery; or their branches: intracranially, coronary artery, femoral artery, popliteal artery, iliac artery, abdominal aorta, the portacaval system, splenic artery, gastric artery, hepatic artery, and superior and inferior mesenteric artery.

In one embodiment, the hydrogel device is in the form of a plug which, for example, occludes the neck of an aneurysm to seal off the sac from the cavity of the parent vessel, artery or vein. The plug may be hollow or solid.

In another embodiment, the hydrogel device is in the form of a tubular stent, which for example, occludes a fistula or a neck of an aneurysm and provides a passage in the cavity. (i.e. maintaining potency of the lumen of the parent artery or vein.)

In practizing the invention, a vascular structure with a peripheral wall defining a cavity and having a localized abnormal wall area is treated by:

a) placing a hydrogel material in the cavity such that an outer surface of the hydrogel material spans the localized abnormal wall; and
b) hydrating and expanding the hydrogel material to thereby cause the hydrogel material to abut an inner surface of the peripheral wall and occlude the localized abnormal wall such that the abnormal wall is sealed from the cavity.

The vascular structure, also referred to as a parent vessel, artery or vein, may have a variety of configurations such as a branched, Y-shaped structure, where an aneurysm forms adjacent an int rsection of branches, or an arteriovenous structure with a closely adjacent vein and artery and an abnormal wall area comprising an opening (fistula) between the closely adjacent vein and artery.

The hydrogel material may simply be used to cut-off flow of blood through the abnormal wall area, such as by plugging the neck of the aneurysm to isolate or seal off the sac while permitting flow through all branches of the vessel. Alternatively, the hydrogel material may be expanded to essentially fill or plug the entire cross-section of a cavity if flow downstream of the abnormal wall is not critical.

In practizing the invention a vascular structure with a localized abnormal wall is treated by:

a) placing the stent of a hydrogel material in a cavity formed by an inner surface of the vascular structure such that an outer surface of the stent crosses over the abnormal wall; and

b) hydrating the stent to expand the wall of the stent to thereby cause the outer surface of the stent to abut the inner surface of the vascular structure at a sealing edge adjacent the abnormal wall, the sealing edge encircling a peripheral extent of the abnormal wall, such that a suitable passage is provided in the cavity through the stent and across the localized abnormal wall.

The hydrogel material is of a polymer network which is capable of absorbing and retaining a significant quantity of water within its network. This water absorption causes the material to expand or swell to a generally predictable degree depending on the initial size and shape. The high water content, flexibility, lack of or negligible toxicity, and strength of the hydrogel material somewhat resemble that of natural body tissue.

Preferably, a hydrogel material used is of the types produced in a process as described in U.S. Patent No. 4,663,358.

The hydrogel stent may conveniently be inserted into the vascular structure using a fluoroscopically guided catheter via the percutaneous puncture of an access vessel, such as the femoral artery or vein, jugular vein, carotid artery and the like. The basic procedure begins with placing the tubular stent on a temporary occlusive balloon catheter. The catheter has an outer diameter which is less than the inner diameter of the stent in both its fully hydrated and dehydrated conditions. The catheter has a balloon on its distal end. The catheter with the stent in place is inserted percutaneously into a vessel in communication with the vascular structure to be treated. The stent is guided along by the catheter to the abnormal wall area and then the balloon is inflated to reduce blood flow so that the stent may be held in place while the stent is being expanded. Once the stent is expanded fully, the balloon is deflated. Then, the catheter is removed and the stent is held in place in the vascular structure, by tension.

The hydrogel stent is conveniently provided as a part of kit used in the percutaneous procedure. The kit includes the stent, the balloon catheter and a guide wire constructed and arranged to direct movement of the catheter for coaxial placement of the stent in the vascular structure.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic view of a vascular structure with an aneurysm.

Figure 2 is a schematic view of the vascular structure of Figure 1, with an implanted device of the invention.

Figure 3 is a schematic view of the vascular structure of Figure 1, with an alternative implanted device of the invention.

Figure 4 is a schematic view of the vascular structure of Figure 1, with the alternative implanted device of the invention in a different arrangement.

Figure 5 is a schematic view of a vascular structure with an arteriovenous fistula.

Figure 6 is a schematic view of the vascular structure of Figure 5, with an implanted device of the invention.

Figure 7 is a schematic view of the vascular structure of Figure 6, with an alternative implanted device of the invention.

Figure 8 is a photograph of an aneurysm in an aorta of a rat.

Figure 9 is a photograph of the aorta of Figure 8, after treatment with the implanted stent of the invention.

Figure 10 is a photograph of a fistula in an aorta vena cava of a rat.

Figure 11 is a photograph of the aorta vena cava of Figure 10, after treatment with the implanted stent of the invention.

Figure 12 is a photograph showing a cross-sectional view of the stent of Figure 11 taken one month after implantation.

Figure 13 is a schematic view of a delivery system for placement of the stent of the invention.

Figure 14 is a schematic view of the delivery system of Figure 13, after inflation of the balloon.

Figure 15 is a schematic view of the delivery system of Figure 13, after removal of the catheter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1 illustrates an abnormal wall area 20, also referred to as a localized abnormal wall, consisting of an aneurysm 22 at a branch of a vascular structure 24. The term vascular structure refers to a vein, artery or vessel. More particularly, vascular structures include: brachiocephalic artery, carotid artery, vertebrae artery; or their

branches: intracranially, coronary artery, femoral artery, popliteal artery, iliac artery, abdominal aorta, the portacaval system, splenic artery, gastric artery, hepatic artery, and superior and inferior mesenteric artery.

As shown in Figure 2, a preferred embodiment of a hycrogel device 28 of the invention, is placed in the vascular structure 24, to treat the aneurysm 22. As shown in Figures 1 and 2, the vascular structure 24 has a cavity 32 defined by an inner surface 36 of a peripheral wall 40 of the vascular structure 24. The hydrogel device 28 is in the form of a tubular stent 44, which becomes expanded by uptake of water from blood present in the vascular structure 24, and held in place essentially permanently by tension between an external surface 48 of the stent 44 and the inner surface 36 of the vascular structure 24.

In one embodiment, the hydrogel stent 44 may conveniently be inserted into the vascular structure 24 using a fluoroscopically guided catheter via the percutaneous puncture of an access vessel, such as the femoral artery or vein, jugular vein, carotid artery and the like. The basic procedure begins with placing the tubular stent 44 on a balloon catheter. The catheter with the stent 44 in place is inserted percutaneously into a vessel in communication with the vascular structure 24 to be treated. The stent 44 is guided along by the catheter to the abnormal wall area 20 and then the stent 44 is held in place while it is expanded. After expansion, the catheter is removed and the stent 44 is held in place in the vascular structure 24, by tension. This procedure is more fully described below.

As shown in Figures 3 and 4, the hydrogel device 28 comprises an alternative embodiment in the form of a plug 52 which, upon expansion by water uptake from blood, occludes or seals off the neck 56 of the aneurysm 22 (Figure 3); or is expanded by uptake of water to occlude both the neck 56 of the aneurysm 22 and the entire cross-section of the cavity 32 of vascular structure 24 in the vicinity of the aneurysm 22 (Figure 4).

The device 28 of the invention may also be used in the stent 44 or plug 52 form to treat vascular structures with abnormal walls such as fistulae or tears of a vessel wall. An example of an arteriovenous fistula 60 in an arteriovenous vascular structure 64 is shown in Figure 5, where the blood flow from an artery 68 is diverted to a vein 72 due to the relatively lower pressure of the vein 72.

Accordingly, in another preferred embodiment, as shown in Figure 6, the stent 44 is placed so as to overlie the opening or fistula 60 between the vein 72 and the artery 68 so as to occlude the fistula 60, permit flow through the stent 44 and thus restore flow toward a direction downstream of the stent in the artery 68.

It should be appreciated that the stent 44 is preferably inserted into the artery 68, however, insertion of the stent 44 into the vein 72 is also possible.

In still another alternative embodiment, the hydrogel plug 52 may be used to occlude the fistulae 60 and further to occlude the cross-section of the cavity 32 of either the vein 72 or artery 68 if desired, depending n the application (Figure 7).

An important factor in the success of the implant device 28 is the choice of the material, namely a hydrogel material. Recently new hydrogel materials particularly those derived from poly(vinyl alcohol) have become available, as described in U.S. Patent No. 4,663,358.

These polymeric hydrogels have a high capacity to absorb and retain water, while the cross-link network prevents dissolution of the individual chains. The high water content, rubbery consistency, low toxicity and low interfacial tension make hydrogels resemble, to some degree, natural tissues. Hydrogels from poly(vinyl alcohol) (PVA) units, provide desired mechanical strength without the need for a cross-linking agent, which may have an adverse effect when implanted.

It is surmised that the integrity of the hydrogel material is primarily derived from hydrogen bonding and the large number of small crystallites. Because of the high tensile strength of the PVA hydrogels, they may be manufactured into very thin but strong devices.

Thus, the stent consists essentially of a hydrogel initially in a less than fully hydrated condition. The hydrogel is formed of a PVA polymer with a degree of polymerization sufficient to form a three dimensional network or polymer crystallites with interspaces between the polymer crystallites. When fully hydrated, the hydrogel stent comprises water in an amount up to about 99% by weight of the hydrogel, with at least a portion of the water occupying the interspaces. The hydrogel stent has a tensile strength and elasticity at least equal to the tensile strength and elasticity of the vascular structure. Preferably, the tensile strength is at least about 100 N/cm^2 and the water content is in the range of 50 to 98% by weight.

While metallic stents are currently being used in vessels and ducts in the body for various reasons, it has been found that the hydrogel stent possesses important properties which render it useful to treat vascular abnormalities by way of internal implant. Key features of the stent as observed during implant include:

a) Variable Size - able to be placed in vessels as small as 4 -5 mm internal diameter.

b) Thin Walled - lined the parent artery without significant decrease in overall lumen cross-sectional area.

c) Smooth - the walls of the stent were non-thrombogenic, and there was no significant intimal hyperplasia due to its presence.

d) Hydrophilic - the material absorbed water over a defined period of time (less than 60 min) and expanded the device. The stent was easily introduced into small vessels, followed by stent expansion to a snug fit within the vessel.

e) Flexible and Pliable - provides a smooth transition between the stented segment over the localized abnormal wall and adjacent wall; and is flexible

even when mounted n the delivery catheter to permit access through tortuous vessels to the localized abnormal wall area.

The shape of the hydrogel stent 44 is that of a hollow tube, which may be cut to nearly any desired length. The wall thickness is also variable, between 25-100 µm as is the inner diameter of the tube.

These variations in tube length and diameter are controlled during manufacturing, and are important because of the variability in sizes of vascular structures and the localized abnormal wall to be treated. The thickness of the wall of the device after absorption is a key factor in the success or failure of these devices. In general, the thinnest wall possible is most desired. Obviously, as wall thickness increases, there is less lumen caliber (passage cross-section of area). Also, abrupt changes in diameter, such as at the inlet and outlet of the stent, will produce alterations in the laminar blood flow, with possible resultant thrombus (clot) formation, separation of the device from the wall of the vascular structure, or even theoretically, aneurysm formation at that site.

The final outer dimension attained by the device after water absorption depends on: 1) initial diameter of the dehydrated stent; and 2) thickness of the wall of the device (i.e. the thicker the wall, the more water which is absorbed, and hence, the larger the final dimensions). Generally, the initial tube outer diameters are between 1 and 3 mm. The degree of expansion upon water uptake ranges from 1:2 and 1:4. The rate of expansion is greatest in distilled water, less in saline and lowest in human or animal blood.

It has been determined that the hydrogel material described above will expand essentially completely in less than 60 minutes, usually 20 to 40 minutes. It will remain expanded despite expected variations in blood chemistry and only becomes dehydrated and contracted upon contact with alcohol in amounts so great that death by alcohol toxicity would be caused before the stent would become dislodged. The hydrogel material described above, begins to melt at a temperature of about 60°C thus death by hyperthermia would be caused at or above about 42°C before the stent would dissolve.

EXAMPLE 1

The stent 44 of the invention, was successfully used to treat an aneurysm in the aorta of a rat. An aneurysm was created in the rat's aorta as shown in Figure 8. The aorta had an internal diameter of about 3mm

A tubular stent 1cm long, 1.8mm in external diameter and with a wall thickness of 75 µm in a dehydrated state, was inserted into the aorta and held in place over the neck of the aneurysm for about 20 minutes, until it expanded to an exterior (outer) diameter of 3mm.

Figure 9 shows the condition of the aorta 30 days after implantation of the tubular stent. As can be seen, the implantation was successful as indicated by:

a) patency of the aorta with the stent in place;
b) lack of filling of the aneurysm;
c) no significant reduction in vessel lumen (cross-sectional area of the parent artery);
d) no detachment or migration of the stent; and
e) the pathology of post-mortem showed no fibroblast foreign body reaction or neo-intima.

EXAMPLE 2

The stent 44 of the invention was successfully used to treat an aorta vena cava fistula in a rat. Prior to creation of the fistula, the aorta had an internal diameter of about 2.8mm and the vena cava had an internal diameter of about 3.8mm. The fistula was created between the vein and aorta as shown in Figure 10, causing blood from the higher pressure aorta vessel to be diverted into the vena cava. The enlarged vena cava is clearly evident. A tubular stent 1cm long, 1.8mm in external diameter and with a wall thickness of 75 µm in a dehydrated state was inserted into the aorta and held in place for about 20 minutes, until it expanded to an exterior (outer) diameter of 2.8mm.

Figure 11 shows the condition of the arteriovenous structure 30 days after implantation of the tubular stent. Success was indicated as per the five factors described in Example 1.

A cross-section of the histology of the stent of the fistula case, (Example 2), is shown in Figure 12, as taken about one month after implantation. A cut was made into the vascular structure to remove the portion of the structure with the implanted stent. In Figure 12, the peripheral wall of the vascular structure is clearly visible as is the outer surface of the hydrogel stent. The stent defines a clearly visible passage or lumen with the post-mortem clot in the cavity of the vascular structure as shown in Figure 12. Pathologic analysis of Figure 12 clearly shows:

a) no inflammatory reaction around the stent;
b) no neo-intima lining the inner surface of the stent;
c) no intima build up at the ends of the stent;
d) permanent stationary position of the stent to the vessel wall; and
e) absence of discernable pre-mortem clot/plaque on the inner surfaces of the stents.

The stents 44 according to the invention, as described in Examples 1 and 2, were implanted into a total of ten rats. All of the rats survived the implantation, however, complications arose in three of the ten trials. One rat developed thrombosis of the distal abdominal aorta, but had excellent collateral circulation. The thrombosis was caused by tight closure of aortotomy,

due to the insertion method used. Two rats died due to repeated attempts to inject dye.

In all ten cases success of the implantation was indicated by lack of gangrene in the tail and lack of heart failure. That is, in the case of the fistula, absence of gangrene in the tail and absence of heart failure indicated that the stent remained in place, closing the fistula. Thus, although death occurred in some cases, postmortem evidence showed the intended result was achieved.

Although not limited to any particular apparatus for inserting the hydrogel device of the invention, preferably, the device is delivered and placed using a fluoroscopically guided catheter via the percutaneous puncture of an access vessel (femoral aratery, femoral vein, internal jugular vein, carotid artery, etc).

As shown in Figs. 13, 14 and 15, the tubular stent 44 is placed on a balloon catheter 80 (Fig. 13). The catheter 80 has an outer diameter which is less than the inner diameter of the stent in both its fully hydrated and dehydrated conditions, and has a balloon 84 on the distal end of the stent 44. The catheter 80 with the stent 44 in place is inserted percutaneously into a vessel 88 in communication with the vascular structure 24 to be treated. The stent 44 is guided along by the catheter 80 to the abnormal wall area 20 and then the balloon 84 is inflated to reduce blood flow so that the stent may be held in place while it is expanded (Fig. 14). Once the stent 44 has been expanded, the catheter 80 is removed and the stent 44 is held in place in the vascular stucture 24, by tension (Fig. 15).

The hydrogel stent is conveniently provided as a part of kit used in the percutaneous procedure. The kit includes the stent 44, the balloon catheter 80 and a guide wire 90 for coaxial placement of the stent in the vascular structure.

Advantageously, the implant and the device apparatus of the invention will significantly improve the treatment of certain vascular lesions in humans, including arteriovenous fistulae, traumatic vascular lesions, some aneurysms, other abnormal wall areas or localized abnormal wall, as well as having other applications.

Claims

1. An implant device (28) to be inserted permanently into a vascular structure (24) for treating a localized abnormal wall (20) of the structure (24), comprising an unexpanded hydrogel which is in a less than fully hydrated condition,

   the unexpanded hydrogel being formed of a polymer with a degree of polymerization sufficient to form a three-dimensional network of polymercrystallites with interspaces between the polymer crystallites,
   wherein the unexpanded hydrogel is formed to a vessel-shape, or a portion thereof, so as to span the localized abnormal wall, or to occlude any opening in said localized abnormal wall, and is capable of absorbing a significant quantity of water within its network causing the implant device (28) to expand, and thereby is held in place.

2. The implant device (28) according to claim 1, wherein the unexpanded hydrogel is a porous PVA hydrogel which has a tensile strength of not less than 100 N/cm^2, a water content of 50 to 98% by weight and is prepared by dissolving polyvinyl alcohol (PVA) in a mixed solvent consisting of water and an organic solvent, followed by crystallization of PVA at temperatures lower than room temperature.

3. The implant device according to claim 1 and 2, wherein said implant device (28) is a tubular stent (44).

4. The implant device according to claim 1 and 2, wherein said implant device (28) is a plug (52).

5. An apparatus for delivery and placement of an implant device (28) to occlude a localized abnormal wall (20) of a vascular stucture (24), the vascular structure being at least one selected from the group consisting of artery, vein and vessel (88), comprising:

   a) a catheter (80) with a first end constructed and arranged for insertion into the vascular structure (24) through a percutaneous vascular access;
   b) an expandable balloon (84) affixed to the first end of the catheter (80);
   c) a hydrogel tubular stent (44) carried on the catheter (80) and characterized by a first internal diameter in a dehydrated condition and a second internal diameter in a hydrated condition, the first and second internal diameters of the stent (44) being greater than the outer diameter of the catheter (80) and less than the peripheral extend of the balloon (84) when expanded, the hydrogel stent (44) further characterized by a three dimensional network of polymer crystallites with interspaces between the polymer crystallites and when fully hydrated, water in an amount up to about 99% by weight of the hydrogel.

6. An apparatus according to claim 5, with a guide wire constructed and arranged to direct movement of the catheter (80) for coaxial placement of the stent (44) in the vascular structure (24).

Patentansprüche

1. Implantat (28), das in eine vaskuläre Struktur (24) zur Behandlung einer örtlichen abnormen Wan-

dung (20) der Struktur (24) dauerhaft einzufügen ist, mit folgenden Merkmalen:

ein unexpandiertes Hydrogel ist in einem weniger als gänzlich hydriertem Zustand;
das unexpandierte Hydrogel wird von einem Polymer mit einem Polymerisationsausmaß gebildet, der ausreicht, ein dreidimensionales Netzwerk von Polymerkristalliten sowie mit Zwischenräumen zwischen den Polymerkristalliten zu bilden;
das unexpandierte Hydrogel wird in eine Gefäßgestalt oder ein Teil hiervon gebracht, um die örtliche abnorme Wandung zu überspannen oder eine Öffnung in der örtlich abnormen Wandung zu schließen, und ist in der Lage, eine beträchtliche Menge Wasser innerhalb des Netzwerks zu absorbieren, was das Implantat (28) dazu bringt, zu expandieren und sich dabei an Ort und Stelle zu halten.

2. Implantat (28) nach Anspruch 1, dadurch gekennzeichnet, daß das unexpandierte Hydrogel ein poröses PVA-Hydrogel darstellt, welches eine Zugfestigkeit nicht unterhalb von 100N/cm^2, einen Wassergehalt von 50 bis 98 Gew.% aufweist und durch Auflösen von Polyvinylalkohol (PVA) in einem gemischten Lösungsmittel präpariert wird, das aus Wasser und einem organischen Lösungsmittel besteht, gefolgt durch die Kristallisation von PVA bei Temperaturen unterhalb der Raumtemperatur.

3. Implantat nach Anspruch 1 oder 2, worin das Implantat (28) einen rohrförmigen Stent (44) darstellt.

4. Implantat nach Anspruch 1 und 2, worin das Implantat (28) einen Stopfen (52) darstellt.

5. Vorrichtung zur Bereitstellung und Plazierung eines Implantats (28), um eine örtliche abnorme Wandung (20) einer vaskulären Struktur (24) zu verschließen, die aus einer Arterie, Vene und/oder ein Gefäß (88) bestehen kann, mit folgenden Merkmalen:

a) ein Katheder (80) ist an einem Ende so konstruiert und angeordnet, daß er in die vaskuläre Struktur (24) über einen perkutanen vaskulären Zugang eingeführt werden kann;
b) ein expandierbarer Ballon (84) ist am ersten Ende des Katheders (80) befestigt;
c) ein rohrförmiger Stent (44) aus Hydrogel wird von dem Katheder (80) getragen und ist durch einen ersten inneren Durchmesser im dehydrierten Zustand sowie durch einen zweiten inneren Durchmesser im hydrierten Zustand charakterisiert, wobei die ersten und zweiten inneren Durchmesser des Stents (44) größer als der Außendurchmesser des Katheders (80) und kleiner als die Umfangsausdehnung des Ballons (84) sind, wenn dieser expandiert ist; der Stent (44) als Hydrogel ist ferner durch ein dreidimensionales Netzwerk aus Polymerkristalliten mit Zwischenräumen zwischen den Polymerkristalliten sowie im völlig hydrierten Zustand durch Wasser in einem Betrag bis zu ungefähr 99 Gew.% des Hydrogels gekennzeichnet.

6. Vorrichtung nach Anspruch 5, gekennzeichnet durch einen Führungsdraht, der so ausgebildet und angeordnet ist, daß er die Bewegung des Katheders (80) zur koaxialen Plazierung des Stent (44) in der vaskulären Struktur (24) lenkt.

Revendications

1. Implant à hydrogel intravasculaire (28) destiné à être inséré de manière permanente dans une structure vasculaire (24) pour le traitement d'une paroi localement anormale (20) de la structure (24), comprenant un hydrogel non expansé qui se trouve dans un état d'hydratation incomplète,

l'hydrogel non expansé est constitué d'un polymère ayant un degré de polymérisation suffisant pour former un réseau tridimensionnel de cristallites polymères avec des interstices entre les cristallites polymères,
dans lequel l'hydrogel non expansé est moulé en forme de vaisseau, ou de portion de vaisseau, de sorte à recouvrir la paroi localement anormale ou à boucher toute ouverture dans ladite paroi localement anormale, et est en mesure d'absorber une quantité significative d'eau au sein de son réseau, provoquant ainsi une expansion de l'implant (28) qui le maintient à l'emplacement choisi.

2. Implant (28) selon la revendication 1, dans lequel l'hydrogel non expansé est un hydrogel en PVA poreux dont la résistance à la traction n'est pas inférieure à 100 N/cm^2, dont la masse comprend de 50 à 98 % d'eau et qui est préparé par dissolution d'alcool polyvinylique (PVA) dans un solvant mixte composé d'eau et d'un solvant organique, suivie d'une cristallisation du PVA à des températures inférieures à la température ambiante.

3. Implant selon les revendications 1 et 2, dans lequel ledit implant (28) est un stent (implant vasculaire) tubulaire (44).

4. Implant selon les revendications 1 et 2, dans lequel ledit implant (28) est un bouchon (52).

5. Appareillage destiné à délivrer et à mettre en place un implant (28) pour occlure une paroi local ment anormale (20) d'une structure vasculaire (24), cette structure vasculaire étant au moins l'une des structures du groupe constitué par les artères, les veines et les vaisseaux (88), qui comprend :

   a) un cathéter (80) avec une première extrémité construite et constituée pour son insertion dans la structure vasculaire (24) par un accès vasculaire percutané ;
   b) un ballon expansible (84) fixé à la première extrémité du cathéter (80) ;
   c) un stent tubulaire en hydrogel (44)) transporté sur le cathéter (80) et caractérisé par un premier diamètre interne à l'état déshydraté et un second diamètre interne à l'état hydraté, les premier et second diamètres internes du stent (44) étant supérieurs au diamètre externe du cathéter (80) et inférieurs à la largeur radiale du ballon (84) à l'état expansé ; le stent en hydrogel (44) est en outre caractérisé par un réseau tridimensionnel de cristallites polymères avec des interstices entre les cristallites polymères et par le fait que la masse de l'hydrogel comprend jusqu'à environ 99 % d'eau quand il est entièrement hydraté.

6. Appareillage selon la revendication 5 avec un câble de guidage construit et constitué pour diriger le déplacement du cathéter (80) de manière à assurer un positionnement coaxial du stent (44) dans la structure vasculaire (24).

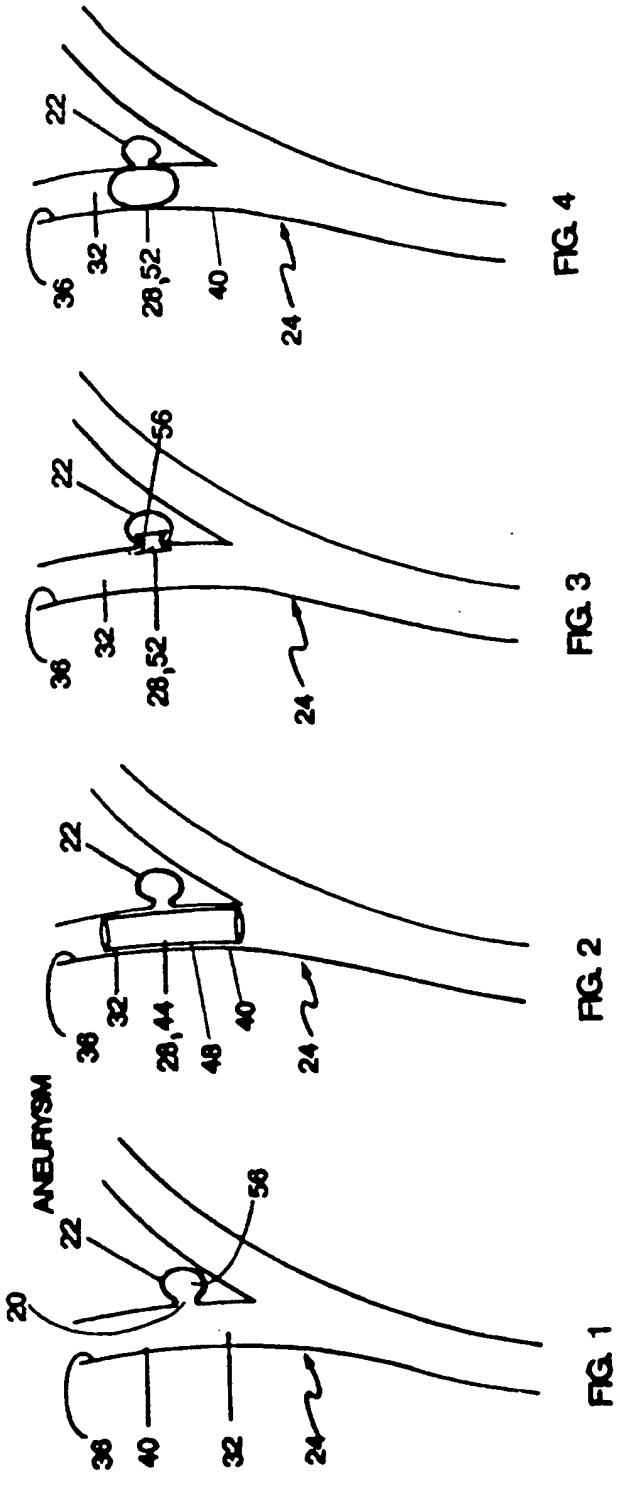

FIG. 1

FIG. 2

FIG. 3

FIG. 4

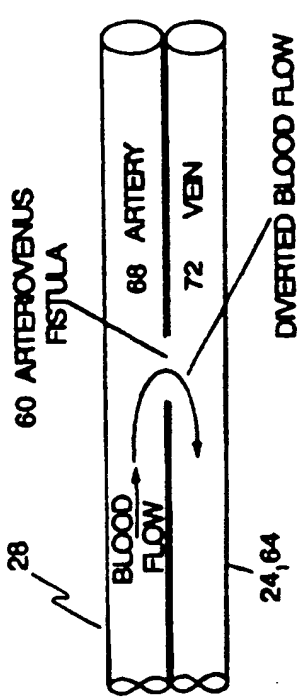

FIG.5

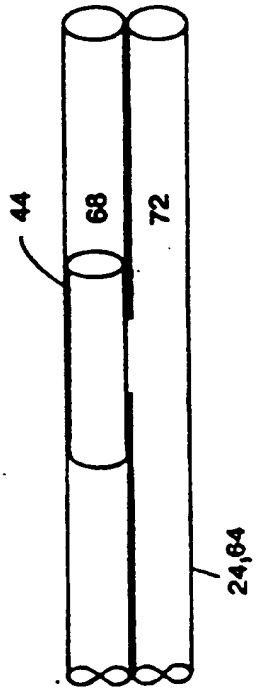

FIG.6

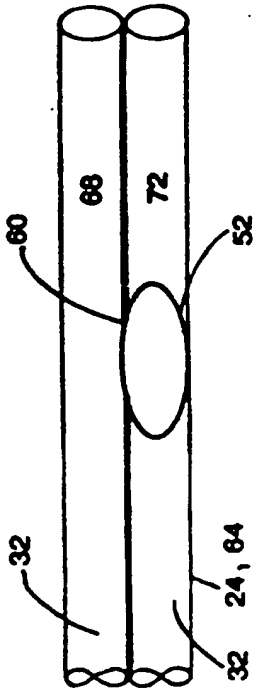

FIG.7

FIG.8

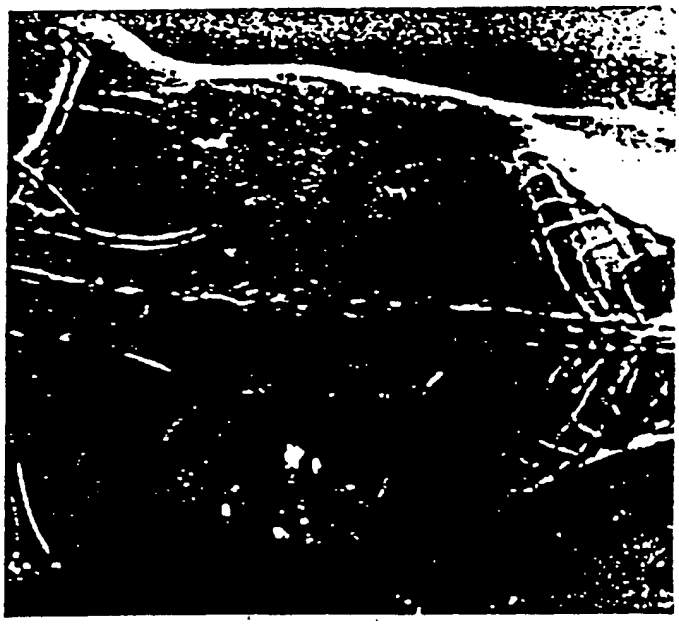

FIG.9

FIG.10

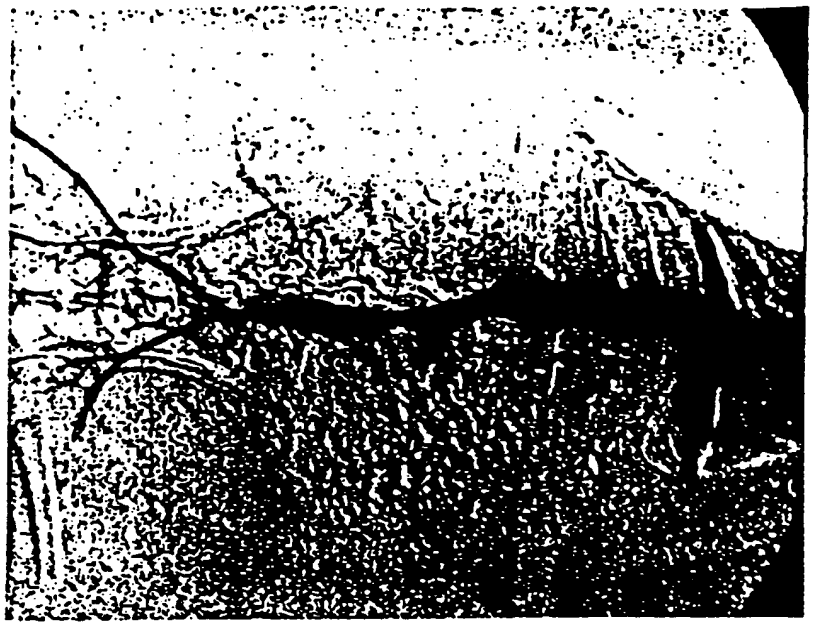

FIG.11

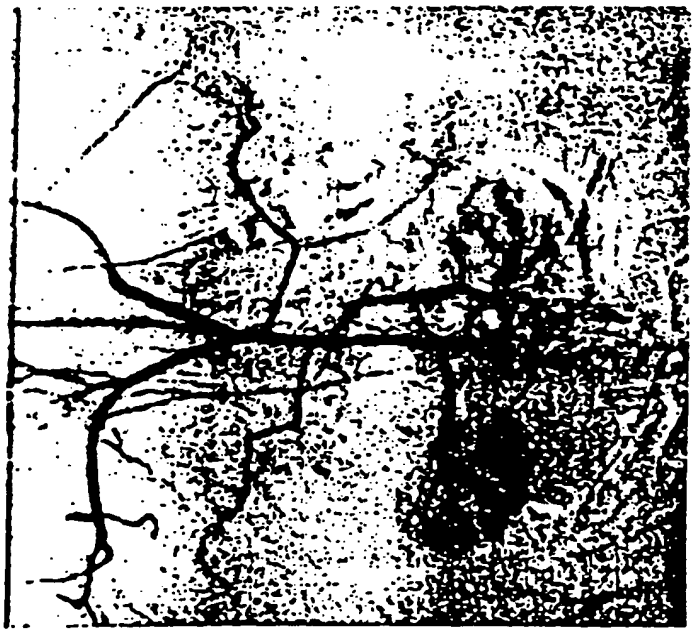

FIG.12

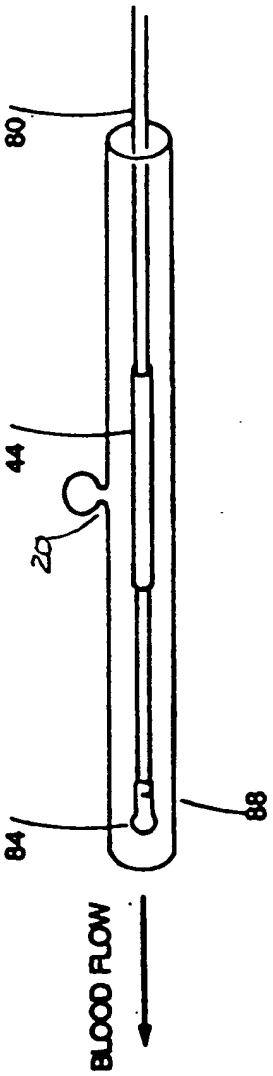

FIG. 13

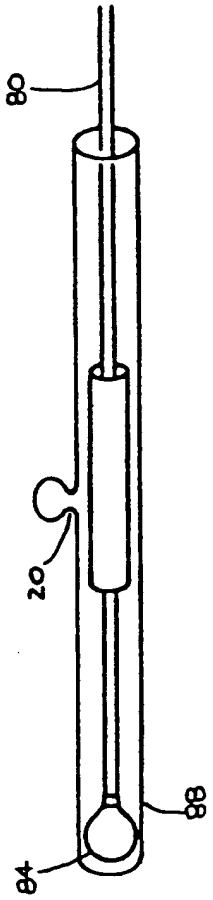

FIG. 14

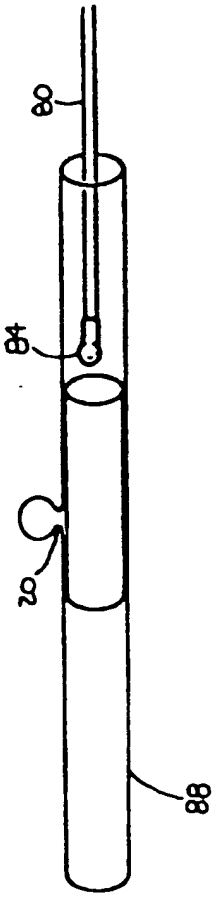

FIG. 15